MAY 1 1 2011

SUMMARY OF SAFETY AND EFFECTIVENESS

Assigned 510(k) Number

The assigned 510(k) number is K100910

Sponsor Name and Address

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA
90045-6900
(310) 645-8200

Contact

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Device Name

Trade name:	IMMULITE® 2000 3gAllergy™ Specific IgE Assay
Classification:	Class II
Classification Names:	Radioallergosorbent (RAST) Immunological Test System
Regulation Number:	866.5750
Product Code:	DHB
Catalog Numbers:	L2KUN6 (600 tests)

Description of Device

IMMULITE® 2000 3gAllergy™ Specific IgE is a solid-phase, two-step, chemiluminescent immunoassay that exploits liquid phase kinetics in a bead format.[1,2] (U.S. Patent No. 4,778,751) It represents a significant advance over conventional methods relying on allergens attached to a solid-phase support, such as a paper disk.

The allergens are covalently bound to a soluble polymer/co-polymer matrix, which in turn is labeled with a ligand. The use of an amino acid co-polymer amplifies the amount of allergen that the matrix can support.

Incubation Cycles: 2 × 30 minutes.

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[1] El Shami AS, Alaba O. Liquid-phase *in vitro* allergen-specific IgE assay with *in situ* immobilization. Adv Biosci 1989;74:191–201.

[2] Alaba O, El Shami AS. Evaluation of non-specific IgE binding: comparison of two *in vitro* allergen assays. Adv Biosci 1989;74:203–14.

Indications for Use

For *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders. The test results are to be used in conjunction with clinical findings and other laboratory tests.

Establishment Information

IMMULITE® 2000 3gAllergy Specific IgE assay is manufactured by Siemens Healthcare Diagnostics Inc. at the following location:

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900
FDA Establishment #: 3005250747

Predicate

The purpose of this 510(k) submission is for clearance of ten additional specific allergens, named in the table below, to be used with the IMMULITE® 2000 3gAllergy™ Specific IgE on the IMMULITE® 2000 analyzer.

1	F237L2 - Apricot	6	F50L2 - Chub Mackerel
2	F261L2 - Asparagus	7	F270L2 - Ginger
3	F288L2 - Blueberry	8	F306L2 - Lime
4	F291L2 - Cauliflower	9	F65L2 - Perch
5	F279L2 - Chili Pepper	10	F236L2 - Whey

FDA clearance was previously obtained for the assay kit and 196 specific allergens and allergen panels (K013134, K021206, K013135 and K021208).

Please note that the FDA clearances indicated above were in the name of Diagnostic Products Corporation which was acquired by Siemens Medical Solutions Diagnostics in July 2006. Siemens Medical Solutions Diagnostics was renamed Siemens Healthcare Diagnostics Inc. on January 1, 2008.

Precision

Precision studies were performed in accordance with Clinical Laboratory Standard Institute (CLSI) guidance: *Evaluation of Precision Performance of Quantitative Methods; Approved Guideline-Second Edition.* CLSI document EP5-A2 (ISBN 1-56238-542-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004, assaying two aliquots of each test sample in two runs per day on 20 different days (Positives 1-3). Additional studies for Positives 4

were done assaying two aliquots of each test sample in two runs per day on 10 different days. Analysis of variance was used to estimate the within-run and total precision.

Three allergen lots were tested using three positive samples and one negative sample. Intra-assay and inter-assay precision for the positive samples were evaluated by calculating the kU/L dose percent coefficients of variation (%CV) for each positive sample. Non-specific binding (NSB) was monitored by testing the negative control sample.

Representative precision claims for each allergen tested are presented below:

Allergen Precision Claims*					
		Within-Run		Total	
Sample	Mean kU/L	SD kU/L	CV %	SD kU/L	CV %
Allergen = Apricot, Lot 114					
Positive #1	15.49	0.538	3.47	0.685	4.42
Positive #2	2.62	0.091	3.49	0.116	4.45
Positive #3	4.30	0.127	2.95	0.164	3.81
Positive #4	0.42	0.028	6.58	0.028	6.69
Allergen = Asparagus, Lot 113					
Positive #1	4.38	0.151	3.46	0.202	4.61
Positive #2	1.16	0.034	2.94	0.039	3.39
Positive #3	1.58	0.067	4.26	0.095	5.98
Positive #4	0.54	0.041	7.52	0.043	7.85

Allergen = Blueberry, Lot 115					
Positive #1	3.72	0.157	4.21	0.200	5.37
Positive #2	7.53	0.245	3.25	0.364	4.83
Positive #3	0.91	0.022	2.46	0.025	2.76
Positive #4	0.46	0.018	3.97	0.019	4.20
Allergen = Cauliflower, Lot 114					
Positive #1	1.25	0.044	3.55	0.058	4.60
Positive #2	4.42	0.163	3.68	0.239	5.39
Positive #3	10.65	0.407	3.82	0.474	4.45
Positive #4	0.49	0.033	6.62	0.044	8.99
Allergen = Chili Pepper, Lot 116					
Positive #1	0.44	0.019	4.31	0.025	5.65
Positive #2	12.88	0.475	3.69	0.582	4.52
Positive #3	5.29	0.216	4.07	0.259	4.88
Positive #4	1.50	0.103	6.84	0.119	7.89
Allergen = Chub Mackerel, Lot 115					
Positive #1	0.23	0.012	5.05	0.014	6.23
Positive #2	1.90	0.072	3.78	0.095	5.02
Positive #3	1.67	0.052	3.10	0.065	3.86
Positive #4	12.75	0.536	4.20	0.581	4.56
Allergen = Ginger, Lot 115					
Positive #1	0.65	0.020	3.02	0.031	4.83
Positive #2	0.51	0.025	4.84	0.027	5.33
Positive #3	9.70	0.329	3.39	0.445	4.58
Positive #4	0.88	0.047	5.35	0.058	6.56
Allergen = Lime, Lot 110					
Positive #1	1.23	0.032	2.61	0.049	4.03
Positive #2	3.53	0.133	3.77	0.166	4.71
Positive #3	9.10	0.266	2.92	0.346	3.80
Positive #4	0.37	0.034	9.15	0.043	11.47
Allergen = Perch, Lot 111					
Positive #1	12.82	0.544	4.24	0.685	5.34
Positive #2	14.86	0.596	4.01	0.752	5.06
Positive #3	0.89	0.038	4.28	0.048	5.42
Positive #4	0.47	0.024	4.99	0.028	5.85

Allergen = Whey, Lot 113					
Positive #1	3.31	0.136	4.11	0.169	5.11
Positive #2	0.70	0.025	3.59	0.026	3.69
Positive #3	1.48	0.071	4.82	0.075	5.09
Positive #4	14.19	0.580	4.09	0.590	4.16

Linearity

For each allergen, two samples were diluted in 2-fold serial dilutions to 5 levels. The undiluted (neat) and diluted samples were tested with the specific allergen to demonstrate linearity at concentrations within the assay limits. Regression statistics for each allergen comparing observed to expected data are presented below.

Linearity

Allergen	Regression Equation	N	Slope 95% CI	Intercept 95% CI
F237 - Apricot	Y=0.992x -0.0483	11	0.960 to 1.024	-0.1487 to 0.0520
F261 - Asparagus	Y=1.001x +0.0411	11	0.974 to 1.028	-0.0099 to 0.0921
F288 - Blueberry	Y=1.001x +0.0396	12	0.974 to 1.028	-0.0597 to 0.1388
F291 - Cauliflower	Y=1.002x +0.0688	10	0.976 to 1.028	-0.0032 to 0.1407
F279 – Chili Pepper	Y=1.010x +0.4801	12	0.969 to 1.052	-0.0739 to 1.0341
F50 – Chub Mackerel	Y=1.015x +0.2718	12	0.968 to 1.062	-0.2001 to 0.7436
F270 - Ginger	Y=0.992x -0.0051	11	0.966 to 1.017	-0.0675 to 0.0573
F306 - Lime	Y=0.999x -0.0175	12	0.981 to 1.018	-0.0737 to 0.0386
F65 - Perch	Y=0.998x -0.1182	12	0.959 to 1.037	-0.2515 to 0.0152
F236 - Whey	Y=0.999x -0.0074	11	0.980 to 1.017	-0.0875 to 0.0728

Specificity (Inhibition) Studies

Specificity of each allergen was verified through competitive inhibition testing using a single serum sample or pool of sera. A negative sample was used to measure the background response.

To initiate the inhibition experiment, 70 µL of undiluted and 3-4 levels of 5-fold serially diluted inhibitor extract were mixed with 250 µL of sample or pool to achieve final inhibitor concentrations of 218.75, 43.75, 8.75, 1.75, 0.35, 0.08, 0.07, 0.02, 0.01, 0.003 µg/mL. This

mixture was incubated at room temperature (15-28 °C) for 1 hour allowing the immunological reaction to occur. Each sample mixture containing the inhibitor extract and the appropriate controls was assayed with 1 lot of each allergen. The percent (%) inhibition was calculated according to the following formula:

$$\left[\frac{(\text{Response of pos. control}_{(\text{pos. sample} - \text{neg. sample})} - \text{sample response with inhibitor extract})}{(\text{Response of pos. control}_{(\text{pos. sample} - \text{neg. sample})})}\right] \times 100$$

The inhibition plots demonstrate that the allergens tested are inhibited by the relevant inhibitor extract in a concentration dependent fashion. Also, the target % inhibition of 50% for the highest inhibitor concentration tested was met. These results indicate specificity of Apricot, Asparagus, Blueberry, Cauliflower, Chili Pepper, Chub Mackerel, Ginger, Lime, Perch and Whey allergens.

Inhibition Using Negative Controls

Additional inhibition studies were conducted to show that the specific allergens are not cross-reacting to the unrelated allergens. Procedures were followed according to CLSI ILA20-A, Appendix-D. Testing was performed using one positive sample with three unrelated allergen extracts at 1 mg/ml. A negative sample was used to measure the background response. Results on the following specific allergen(s) were below 9.9% for Asparagus, Blueberry, Cauliflower and Perch: Apricot, Chili Pepper, Chub Mackerel, Ginger, Lime and Whey.

Clinical Performance Studies

Clinical performance was demonstrated by testing serum samples against specific allergens from clinically diagnosed atopic and non-atopic individuals. Allergen-specific testing was obtained using the IMMULITE® 2000 3gAllergy™ assay.

Data summary agreement of the IMMULITE® 2000 3gAllergy results to clinical data is presented in the table below.

IMMULITE® 2000	Clinical Data				
	Clinical	Normal	Total		
Positive	282	37	319		
Negative	114	965	1,079		
Total	396	1,002	1,398		
	71.2%	96.3%	89.2%		
	Sensitivity	Specificity	Agreement		
Lower Conf	**67%**	**95%**	**88%**		
Upper Conf	**76%**	**97%**	**91%**		

Allergens included: Apricot, Asparagus, Blueberry, Cauliflower, Chili Pepper, Chub Mackerel, Ginger, Lime, Perch and Whey.

IMMULITE® 2000 3gAllergy assay results for all allergens compare well with clinical documentation of presence or absence of signs, symptoms and other diagnostic evidence of allergen sensitivity.

Conclusions for all Studies

Allergens including Apricot, Asparagus, Blueberry, Cauliflower, Chili Pepper, Chub Mackerel, Ginger, Lime, Perch and Whey for use with the IMMULITE® 2000 3gAllergy Specific IgE assay demonstrate acceptable analytical performance including precision, linearity and specificity. IMMULITE® 2000 assay results compare well with clinical documentation of presence or absence of signs, symptoms and other diagnostic evidence of allergen sensitivity. Substantial equivalence was demonstrated to clinical data, supporting the following intended use of the IMMULITE® 2000 3gAllergys Specific IgE assay and the twenty seven previously listed allergens:

> For *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders. The test results are to be used in conjunction with clinical findings and other laboratory tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics Inc.
c/o Ms. Donna Velasquez
Regulatory Technical Specialist
5210 Pacific Concourse Drive
Los Angeles, CA 90045

MAY 1 1 2011

Re: k100910
Trade/Device Name: IMMULITE® 2000 3G Allergy™ Specific IgE Assay
Regulation Number: 21 CFR §866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Codes: DHB
Dated: March 08, 2011
Received: March 11, 2011

Dear Ms. Velasquez :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K100910

Device Name: IMMULITE 3gAllergy™ Specific IgE Assay

Indication For Use:

For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders. The test results are to be used in conjunction with clinical findings and other laboratory tests.

Prescription Use ___√___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k100910